

# The effect of inspiratory oxygen fraction on the ratio of partial arterial oxygen pressure and inspiratory oxygen fraction (PaO<sub>2</sub>/FiO<sub>2</sub> ratio) in mechanically ventilated patients with and without mild to moderate ARDS

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To study the relation between PaO<sub>2</sub>/FiO<sub>2</sub>-ratio and FiO<sub>2</sub>

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47790

### Source

ToetsingOnline

### Brief title

The effect of FiO<sub>2</sub> on PaO<sub>2</sub>/FiO<sub>2</sub> ratio

### Condition

- Other condition

### Synonym

PaO<sub>2</sub>/FiO<sub>2</sub> ratio

### Health condition

De PaO<sub>2</sub>/FiO<sub>2</sub> ratio wordt bestudeerd

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ARDS, mechanical ventilation, oxygen, PaO<sub>2</sub>/FiO<sub>2</sub> ratio

## Outcome measures

### Primary outcome

The relationship between FiO<sub>2</sub> and PaO<sub>2</sub>/FiO<sub>2</sub>-ratio

### Secondary outcome

Shunt fraction, arteriovenous oxygen difference and alveolar - arterial oxygen

difference will be determined in these patients to explain the relationship

between FiO<sub>2</sub> and the PaO<sub>2</sub>/FiO<sub>2</sub>-ratio

## Study description

### Background summary

The PaO<sub>2</sub>/FiO<sub>2</sub> ratio is frequently used to determine the severity of lung injury in mechanically ventilated patients. However, several mathematical models have shown that PaO<sub>2</sub>/FiO<sub>2</sub> ratio depends on FiO<sub>2</sub>. The relationship is complex and depends on numerous physiological variables, including shunt fraction, and arterio-venous oxygen difference. The nonlinear relation between PaO<sub>2</sub>/FiO<sub>2</sub> and FiO<sub>2</sub> underlines the limitations describing the intensity of hypoxemia using PaO<sub>2</sub>/FiO<sub>2</sub> and is thus of major importance for the clinician. Surprisingly, this relationship has only been assessed mathematically. Obviously, the accuracy of the mathematical relationship depends on the input variables used. The current study is designed to assess the PaO<sub>2</sub>/FiO<sub>2</sub> vs FiO<sub>2</sub> relation in clinical practice.

### Study objective

To study the relation between PaO<sub>2</sub>/FiO<sub>2</sub>-ratio and FiO<sub>2</sub>

## **Study design**

An unblinded, prospective, interventional study

## **Intervention**

Two interventions will be performed:

1. Modulation of FiO<sub>2</sub>: FiO<sub>2</sub> will be reduced to 21% or until peripheral oxygen saturation of 92%, whatever occurs first. Subsequently FiO<sub>2</sub> will be increased up to 100%.
2. Withdrawal of blood: Blood will be withdrawn from the indwelling arterial line and pulmonary artery catheter. No catheters will be inserted for the study. The maximum number of time points is 7. At each time point 1.5 ml of blood will be withdrawn from both the arterial and pulmonary artery catheter for blood gas analysis. At the start and the end of the study period 2 additional blood samples of 5 ml each will be drawn. Accordingly, the maximum amount of blood obtained will be less than 50 ml.

## **Study burden and risks**

The risk and burden for study subjects is negligible. Blood will be withdrawn from the indwelling arterial line and the pulmonary artery catheter. The insertion of arterial and pulmonary artery catheters are part of standard ICU care. Pulmonary artery catheters will not be inserted just for the purpose of the study. The maximum amount of blood obtained will be less than 50 ml. This limited amount of blood will not result in adverse events for the patients participating. For individual patients no benefits are expected.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Mechanically ventilated patients, admitted to the ICU, without ARDS or with mild ( $200 \text{ mmHg} < \text{PaO}_2/\text{FIO}_2 \leq 300 \text{ mmHg}$  with  $\text{PEEP} \geq 5 \text{ cmH}_2\text{O}$ ) to moderate ( $100 \text{ mmHg} < \text{PaO}_2/\text{FIO}_2 \leq 200 \text{ mmHg}$  with  $\text{PEEP} \geq 5 \text{ cmH}_2\text{O}$ ) ARDS (according to the Berlin criteria):

- Stable hemodynamics
- Stable haemoglobin level
- Stable body temperature
- Stable level of sedation
- Pulmonary-Artery and Artery catheter

### Exclusion criteria

- Incomplete revascularization after CABG
- Cardiac ischemia
- Neurotrauma
- Severe ARDS ( $\text{PaO}_2/\text{FIO}_2 \leq 100 \text{ mmHg}$  with  $\text{PEEP} \geq 5 \text{ cmH}_2\text{O}$ )

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-09-2017
Enrollment:	35
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia
Generic name:	Oxygen
Registration:	Yes - NL intended use

## Ethics review

Approved WMO	
Date:	26-06-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO	
Date:	24-07-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO	
Date:	12-10-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO	
Date:	08-06-2018

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-07-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
EudraCT	EUCTR2017-002022-20-NL
ClinicalTrials.gov	NCT03156218
CCMO	NL61945.029.17